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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/409,260	09/30/1999	JEFFREY D. SAFFER	01413.0010	5111

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary**Application No.**

09/409,260

Applicant(s)

SAFFER ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>2 Sheets</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1 Sheet</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on 04 March 2004 has been entered.

Applicants' arguments, filed 04 March 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 14-22.

EXAMINER COMMENT

The following prior art reference(s) for the below 35 U.S.C. § 102(b) and 103(a) rejections were applied in the previous office actions, mailed 07 June 2002 and 09 April 2003. Applicants' are to note the 'Examiner Comment' in the office action mailed 04 November 2003, wherein Applicants were warned "that should arguments and/or amendments be presented such that Applicants "sequence data" represents any "attribute" the rejections under 35 U.S.C. § 102 and 35 U.S.C. § 103 maybe reapplied. Applicants' remarks filed 13 January 2002 and 07 August 2003 pertaining to the prior art references were considered.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 15, and 19-24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Eisen et al. (Cluster analysis and display of genome-wide expression patterns, *Proc. Natl. Acad. Sci. USA*, 1998).

Eisen et al. describes a system of cluster analysis for genome-wide expression data from DNA (nucleic acid; claim 19) microarray hybridization utilizing statistical algorithms to arrange genes according to similarity pattern of gene expression (Abstract). The authors have applied hierarchical cluster analysis to gene expression data, representing relationships among genes by a tree whose branch lengths reflect the degree of similarity between genes (page 14863, Column 2, lines 36-43). The computed trees can then be used to order genes in the original data table, so that genes or groups of genes with similar expression patterns are adjacent (claim 23; page 14863, Column 2, lines 50-53). Data analyzed was obtained from spotted DNA microarrays and the results placed in a table (square matrix; claim 14); wherein rows represent all genes for which data has been collected, columns representing individual array experiments (claim 15), and each cell representing the measure of fluorescence corresponding to the array (page 14864, Column 1, lines 23-28). A gene similarity metric (high dimensional vector; claim 14) (page 14864, Column 1, lines 39-55) is utilized followed by hierarchical clustering software implemented on a computer (claims 20-23), which computes a dendrogram (distance matrix; claims 14 and 24) by

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assembling all elements into a single tree (page 14864, Columns 1-2, lines 55-62 through 1-11, respectively). The data table is represented graphically (square matrix) each cell is colored based on the measured fluorescence and a dendrogram is appended to the colored table, indicating the relationship among genes (page 14864, Column 2, lines 23-25). Patterns of interest can be readily identified; zooming in on the detailed expression patterns and the genes contributing to these patterns (page 14864, Column 2, lines 52-55). The authors illustrate the application of the described method to data measured from cDNA microarray (8,600 human genes) from a time course of serum stimulation of primary human fibroblasts in a clustered display, wherein each gene is represented by a single row of colored boxes and each time point is represented by a single column (Figure 1). Thus, Eisen et al. clearly anticipates the claimed invention by performing the basic steps of: 1) sequence data comparison (i.e. expression data); 2) arrangement of expression comparison results in a square matrix; 3) creation of a high-dimensional vector; and 4) projection of the context vectors onto a viewing area.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eisen et al. (Cluster analysis and display of genome-wide expression patterns, *Proc. Natl. Acad. Sci. USA*, 1998); taken in view of Altschul et al. CLAM 18 (protein)

Eisen et al. describes a system of cluster analysis for genome-wide expression data from DNA microarray hybridization (Refer to the above 35 U.S.C. § 102(b) Rejection). However, Eisen et al. fails to describe the utilization of a Basic Alignment Search Tool or expectancy to compare biopolymer material (nucleic acid or protein).

Altschul et al. describes a rapid sequence comparison approach, Basic Alignment Search Tool (BLAST), which directly approximates alignments that optimize a measure of local similarity, the maximal segment pair score (MSP) (claim 16; Abstract). The method will detect weak but biologically significant sequence similarities (claim 18; page 404, Column 1, lines 6-9). Alignment scores are expressed as expectancy (MSP) (claim 17; page 404, Column 1, lines 40-53).

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to bring out the inherent structures in data to correlate sequence similarity with sequence expression levels to convey the quantitative information more effectively by practicing Eisen et al. (system of cluster analysis for genome-wide expression data utilizing a cDNA microarray of 8,600 human genes) with Altschul et al. (Basic Alignment Search Tool). Since Altschul et al. indicates that the Basic Alignment Search Tool can be applied to DNA sequence similarity analysis and Eisen et al. states the need to find alternative algorithms to more effectively determine inherent structures in the data (page 14867, column 2, lines 4-8). In addition, applicants disclosure defines "context vector"/"sequence data" in such a broad and general concept that said "context vectors"/"sequence data" maybe represented as any data pertaining to a sequence (refer to the above 35 U.S.C. § 102 Rejection).

No Claims Are Allowed.

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EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *May 27, 2004*

Examiner Initials: *CSM*

MPW
MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

5/27/04